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Dr. Reddy's Laboratories Inc., and  
Dr. Reddy's Laboratories Ltd.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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ESPERION THERAPEUTICS, INC.,

Plaintiff,

v.

DR. REDDY'S LABORATORIES INC., and  
DR. REDDY'S LABORATORIES LTD.,

Defendants.

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**Civil Action No. 24-06391-JXN-CLW**

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Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") (collectively, "Defendants" or "DRL"), hereby provide their answers and assert the following defenses to the First Amended Complaint for Patent Infringement of Esperion Therapeutics, Inc. ("Plaintiff" or "Esperion") as follows.

**GENERAL DENIAL**

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in Plaintiffs Complaint for Patent Infringement except those specifically admitted below.

**NATURE OF ACTION**

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "DRL"). This action arises out of DRL's submission of Abbreviated New Drug Application ("ANDA") Nos. 219312 and 219331 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NEXLETOL® and NEXLIZET® prior to the expiration of U.S. Patent Nos. 7,335,799, 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584.

**ANSWER:** Paragraph 1 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the First Amended Complaint purports to state a claim for alleged patent infringement. DRL further admits that Dr. Reddy's Ltd. submitted Abbreviated New Drug Application No. 219312 ("DRL's BA ANDA") to the United States Food and Drug Administration ("FDA") seeking approval for bempedoic acid tablets, 180 mg ("DRL's BA ANDA Product") prior to the expiration of U.S. Patent Nos. 7,335,799 ("the '799 patent"), 11,613,511 ("the '511 patent"), 11,760,714 ("the '714 patent") and 11,926,584 ("the '584 patent"). DRL further admits that Dr. Reddy's Ltd. submitted an Abbreviated New Drug Application No. 219331 ("DRL's BA+E ANDA") to the FDA seeking approval for bempedoic acid and ezetimibe tablets, 180 mg/10 mg ("DRL's BA+E ANDA Product") prior to the expiration of the '799 patent, U.S. Patent No. 10,912,751 ("the '751 patent"), the '511 patent, U.S. Patent

No. 11,744,816 (“the ‘816 patent”), the ’714 patent, and the ’584 patent (collectively, “Asserted Patents”). DRL denies any and all remaining allegations of Paragraph 1.

### **THE PARTIES**

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

**ANSWER:** Paragraph 2 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL is without information sufficient to form a belief as to the remaining allegations in Paragraph 2, and therefore denies the same.

3. Upon information and belief, Defendant Dr. Reddy’s Laboratories Inc. (“DRL Inc.”) is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

**ANSWER:** Paragraph 3 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Dr. Reddy’s Inc. is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. DRL denies any and all remaining allegations of Paragraph 3.

4. Upon information and belief, DRL Inc. is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

**ANSWER:** Paragraph 4 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy’s Inc. is an authorized U.S. Regulatory Agent for Dr. Reddy’s Ltd. for purposes of DRL’s BA ANDA and DRL’s BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 4.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("DRL Ltd.") is a corporation organized and existing under the laws of India, having a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, 500034, India.

**ANSWER:** Paragraph 5 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Dr. Reddy's Ltd. is an entity organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500034, India, which is in the state of Telangana. DRL denies any and all remaining allegations of Paragraph 5.

6. Upon information and belief, DRL Ltd. is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

**ANSWER:** Paragraph 6 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Ltd. submitted DRL's BA ANDA and DRL's BA+E ANDA to FDA. DRL denies any and all remaining allegations of Paragraph 6.

7. Upon information and belief, DRL Inc. and DRL Ltd. working in concert directly or through their affiliates market and sell drug products throughout the United States, including in the state of New Jersey.

**ANSWER:** Paragraph 7 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

8. Upon information and belief, DRL Ltd. is the holder of FDA Drug Master File No. 36933.

**ANSWER:** Paragraph 8 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that FDA's list of Drug Master Files identifies "DR REDDYS LABORATORIES LTD" as the "HOLDER" of Drug Master File No. 36933. DRL denies any and all remaining allegations of Paragraph 8.

9. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd.

**ANSWER:** Paragraph 9 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Inc. is a subsidiary of Dr. Reddy's Ltd. DRL denies any and all remaining allegations of Paragraph 9.

10. Upon information and belief, DRL Ltd. directs or controls the operations, management, and activities of DRL Inc. in the United States.

**ANSWER:** Paragraph 10 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

11. Upon information and belief, DRL Inc. and DRL Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group.

**ANSWER:** Paragraph 11 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Inc. is an authorized U.S. Regulatory Agent for Dr. Reddy's Ltd. for purposes of DRL's BA ANDA and DRL's BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 11.

12. Upon information and belief, DRL Inc. and DRL Ltd. act in concert to directly or through their affiliates market and sell drug products throughout the United States, including in New Jersey.

**ANSWER:** Paragraph 12 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

13. Upon information and belief, DRL Inc. and DRL Ltd. work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

**ANSWER:** Paragraph 13 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

14. Upon information and belief, DRL Inc. and DRL Ltd., acting in concert, prepared, and submitted ANDA No. 219312 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the “DRL NEXLETOL® ANDA Product”) prior to the expiration of U.S. Patent Nos. 7,335,799, 11,760,714, 11,613,511 and 11,926,584.

**ANSWER:** Paragraph 14 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

15. Upon information and belief, DRL Inc. and DRL Ltd., acting in concert, developed the DRL NEXLETOL® ANDA Product.

**ANSWER:** Paragraph 15 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

16. Upon information and belief, DRL Inc. and DRL Ltd., acting in concert, are seeking regulatory approval from the FDA to market and sell the DRL NEXLETOL® ANDA Product throughout the United States, including in New Jersey.

**ANSWER:** Paragraph 16 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

17. Upon information and belief, DRL Inc. and DRL Ltd. intend to obtain approval for DRL’s ANDA No. 219312, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the DRL NEXLETOL® ANDA Product in the United States, including in New Jersey.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

18. Upon information and belief, DRL Inc. and DRL Ltd., acting in concert, prepared and submitted ANDA No. 219331 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLIZET® (the “DRL NEXLIZET® ANDA Product”) prior to the expiration of U.S. Patent Nos. 7,335,799, 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584.

**ANSWER:** Paragraph 18 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

19. Upon information and belief, DRL Inc. and DRL Ltd., acting in concert, developed the DRL NEXLIZET® ANDA Product.

**ANSWER:** Paragraph 19 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

20. Upon information and belief, DRL Inc. and DRL Ltd., acting in concert, are seeking regulatory approval from the FDA to market and sell the DRL NEXLIZET® ANDA Product throughout the United States, including in New Jersey.

**ANSWER:** Paragraph 20 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

21. Upon information and belief, DRL Inc. and DRL Ltd. intend to obtain approval for DRL's ANDA No. 219331, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the DRL NEXLIZET® ANDA Product in the United States, including in New Jersey.

**ANSWER:** Paragraph 21 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

### **JURISDICTION AND VENUE**

22. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

**ANSWER:** Paragraph 22 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, and for the purposes of this case only, DRL does not contest that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. DRL denies any and all remaining allegations of Paragraph 22.

23. This Court has personal jurisdiction over DRL Inc. because, on information and belief, DRL Inc. is a company organized and existing under the laws of the state of New Jersey, is qualified to do business in New Jersey, and has its principal place of business in New Jersey.

**ANSWER:** Paragraph 23 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest personal jurisdiction over Dr. Reddy's

Inc. solely for the limited purposes of this action only. Further answering, DRL admits that Dr. Reddy's Inc. is an entity organized and existing under the laws of the State of New Jersey, and has its principal place of business in New Jersey. DRL denies any and all remaining allegations of Paragraph 23.

24. In view of the foregoing, DRL. Inc. is subject to general personal jurisdiction in New Jersey.

**ANSWER:** Paragraph 24 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest personal jurisdiction over Dr. Reddy's Inc. solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 24.

25. This Court has personal jurisdiction over DRL Ltd. because DRL Ltd., in concert with its subsidiary DRL Inc., among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219312 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219312, DRL Ltd., in concert with its subsidiary DRL Inc., will make, use, import, sell, and/or offer for sale the DRL NEXLETOL® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 7,335,799, 11,760,714, 11,613,511, and 11,926,584.

**ANSWER:** Paragraph 25 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction over Dr. Reddy's Ltd. solely for the limited purposes of this action only.

26. This Court has personal jurisdiction over DRL Ltd. because DRL Ltd., in concert with its subsidiary DRL Inc., among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219331 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219331, DRL Ltd., in concert with its subsidiary DRL Inc., will make, use, import, sell, and/or offer for sale the DRL NEXLIZET® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 7,335,799, 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584.

**ANSWER:** Paragraph 26 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction over Dr. Reddy's Ltd. solely for the limited purposes of this action only.

27. This Court also has personal jurisdiction over DRL Ltd. because, among other things, this action arises from DRL Ltd.'s, and its subsidiary DRL Inc.'s, concerted actions directed toward New Jersey, and because, upon information and belief, DRL Ltd., and its subsidiary DRL Inc., have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; (3) creating a presence in New Jersey through the registration of DRL Inc. with both the New Jersey Division of Revenue and Enterprise Services, as a business operating in New Jersey under Business Entity ID No. 0100518911, and the New Jersey Department of Health, as a drug manufacturer and wholesaler, and maintaining a Drug and Medical Device Certificate under Registration No. 5002312; and (4) working in concert to develop and market pharmaceutical products, including in New Jersey, with its subsidiary DRL Inc., a corporation organized and existing under the laws of the State of New Jersey. DRL Ltd. has, therefore, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

**ANSWER:** Paragraph 27 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction over Dr. Reddy's Ltd. solely for the limited purposes of this action only.

28. In addition, this Court has personal jurisdiction over DRL Ltd. because, among other things, upon information and belief, (1) DRL Ltd. in concert with its subsidiary DRL Inc. filed their ANDAs for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the DRL NEXLETOL® ANDA Product and the DRL NEXLIZET® ANDA Product in the United States, including in New Jersey, and (2) upon approval of DRL Inc. and DRL Ltd.'s ANDAs, they will market, distribute, offer for sale, sell, and/or import the DRL NEXLETOL® ANDA Product and the DRL NEXLIZET® ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of these DRL ANDA Products in New Jersey. Upon information and belief, upon approval of DRL. Inc. and DRL Ltd.'s ANDAs, the DRL NEXLETOL® ANDA Product and the DRL NEXLIZET® ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

**ANSWER:** Paragraph 28 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction over Dr. Reddy's Ltd. solely for the limited purposes of this action only.

29. This Court also has personal jurisdiction over DRL Ltd. because DRL Ltd. regularly engages in patent litigation in this forum, and affirmatively avail itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction including in at least *Novo Nordisk Inc. v. Dr. Reddy's Labs., Ltd.*, 23-cv- 22112, Dkt. No. 12 (D.N.J. filed Feb. 5, 2024); *Merck Sharp & Dohme BV v. Dr. Reddy's Labs., Inc.*, 20-cv-02909, Dkt. No. 11 (D.N.J. filed Jun. 8, 2020); and *AstraZeneca LP v. Dr. Reddy's Labs. Ltd.*, 19-cv-15739, Dkt. No. 11 (D.N.J. filed Jan. 10, 2020).

**ANSWER:** Paragraph 29 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction over Dr. Reddy's Ltd. solely for the limited purposes of this action only.

30. This Court also has personal jurisdiction over DRL Ltd. because, upon information and belief, DRL Ltd. worked with its subsidiary DRL Inc. in New Jersey to prepare the certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certifications”) regarding ANDA Nos. 219312 and 219331, and designated, pursuant to 21 C.F.R. § 314.95(c)(9), its New Jersey in-house counsel, Anjum Swaroop, PhD., Esq. of DRL Inc., to be its agent in the United States authorized to accept service of process in New Jersey on both DRL Inc. and DRL Ltd.’s behalf in relation to its ANDA Nos. 219312 and 219331.

**ANSWER:** Paragraph 30 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest personal jurisdiction over Dr. Reddy’s Ltd. solely for the limited purposes of this action only.

31. Based on the foregoing systematic and continuous contacts with New Jersey, DRL Ltd. is subject to specific personal jurisdiction in New Jersey.

**ANSWER:** Paragraph 31 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction over Dr. Reddy’s Ltd. solely for the limited purposes of this action only.

32. Upon information and belief, DRL Ltd.’s contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent DRL Ltd. denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over DRL Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because DRL Ltd. is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

**ANSWER:** Paragraph 32 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

33. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for DRL Inc. and DRL Ltd. to litigate this action in this Court, and DRL Inc. and DRL Ltd. are subject to personal jurisdiction in New Jersey.

**ANSWER:** Paragraph 33 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

34. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

**ANSWER:** Paragraph 34 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 34.

35. Venue is proper in this Court as to DRL Inc. under 28 U.S.C. § 1400(b) because it is a company organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this Court, as set forth above, has committed acts of infringement, and, upon information and belief, will commit further acts of infringement in New Jersey.

**ANSWER:** Paragraph 35 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 35.

36. Venue is proper in this Court as to DRL Ltd. under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, DRL Ltd. is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

**ANSWER:** Paragraph 36 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 36.

37. Venue is also proper in this Court for DRL Ltd. because, among other things, DRL Ltd. has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) acted in concert with its subsidiary DRL Inc. to seek approval from the FDA to market and sell the DRL NEXLETOL® ANDA Product and the DRL NEXLIZET® ANDA Product in New Jersey; and (2) in concert with its subsidiary DRL Inc. engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

**ANSWER:** Paragraph 37 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL does not contest venue solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 37.

### **THE PATENTS-IN-SUIT**

38. U.S. Patent No. 7,335,799 (the “’799 Patent”), entitled “Hydroxyl Compounds and Compositions for Cholesterol Management and Related Uses,” was duly and legally issued on February 26, 2008. A true and correct copy of the ’799 Patent is attached hereto as “Exhibit A.”

**ANSWER:** Paragraph 38 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the United States Patent and Trademark Office (“USPTO”), the ’799 patent, titled “HYDROXYL COMPOUNDS AND COMPOSITIONS FOR CHOLESTEROL MANAGEMENT AND RELATED USES,” issued on or about February 26, 2008. DRL denies that the ’799 patent was “duly and legally issued,” and any suggestion or implication that the ’799 patent is valid or enforceable. DRL also admits that a purported copy of the ’799 patent is attached as Exhibit A to the First Amended Complaint. DRL denies any and all remaining allegations of Paragraph 38.

39. Esperion is the assignee of, and holds all rights, title, and interest in the ’799 Patent.

**ANSWER:** Paragraph 39 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, “ESPERION THERAPEUTICS, INC.” is identified as the current assignee of the ’799 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 39, and therefore denies any and all remaining allegations of Paragraph 39.

40. The ’799 Patent currently expires on December 3, 2030.

**ANSWER:** Paragraph 40 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA’s publication, Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”), identifies the purported expiration date of the ’799 patent as December 3, 2030. DRL lacks knowledge or

information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 40, and therefore denies any and all remaining allegations of Paragraph 40.

41. U.S. Patent No. 11,760,714 (the “’714 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on September 19, 2023. A true and correct copy of the ’714 Patent is attached hereto as “Exhibit B.”

**ANSWER:** Paragraph 41 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the ’714 patent, titled “METHODS OF MAKING BEMPEDOIC ACID AND COMPOSITIONS OF THE SAME,” issued on or about September 19, 2023. DRL denies that the ’714 patent was “duly and legally issued,” and any suggestion or implication that the ’714 patent is valid or enforceable. DRL also admits that a purported copy of the ’714 patent is attached as Exhibit B to the First Amended Complaint. DRL denies any and all remaining allegations of Paragraph 41.

42. Esperion is the assignee of, and holds all rights, title, and interest in the ’714 Patent.

**ANSWER:** Paragraph 42 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, “ESPERION THERAPEUTICS, INC.” is identified as the current assignee of the ’714 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 42, and therefore denies any and all remaining allegations of Paragraph 42.

43. The ’714 Patent currently expires on June 19, 2040.

**ANSWER:** Paragraph 43 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA’s Orange Book identifies the purported expiration date of the ’714 patent as June 19, 2040. DRL lacks

knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 43, and therefore denies any and all remaining allegations of Paragraph 43.

44. U.S. Patent No. 11,613,511 (the “’511 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on March 28, 2023. A true and correct copy of the ’511 Patent is attached hereto as “Exhibit C.”

**ANSWER:** Paragraph 44 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the ’511 patent, titled “METHODS OF MAKING BEMPEDOIC ACID AND COMPOSITIONS OF THE SAME,” issued on or about March 28, 2023. DRL denies that the ’511 patent was “duly and legally issued,” and any suggestion or implication that the ’511 patent is valid or enforceable. DRL also admits that a purported copy of the ’511 patent is attached as Exhibit C to the First Amended Complaint. DRL denies any and all remaining allegations of Paragraph 44.

45. Esperion is the assignee of, and holds all rights, title, and interest in the ’511 Patent.

**ANSWER:** Paragraph 45 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, “ESPERION THERAPEUTICS, INC.” is identified as the current assignee of the ’511 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 45, and therefore denies any and all remaining allegations of Paragraph 45.

46. The ’511 Patent currently expires on June 19, 2040.

**ANSWER:** Paragraph 46 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA’s Orange Book identifies the purported expiration date of the ’511 patent as June 19, 2040. DRL lacks

knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 46, and therefore denies any and all remaining allegations of Paragraph 46.

47. U.S. Patent No. 10,912,751 (the “’751 Patent”), entitled “Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease,” was duly and legally issued on February 9, 2021. A true and correct copy of the ’751 Patent is attached hereto as “Exhibit D.”

**ANSWER:** Paragraph 47 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the ’751 patent, titled “FIXED DOSE COMBINATIONS AND FORMULATIONS COMPRISING ETC1002 AND EZETIMIBE AND METHODS OF TREATING OR REDUCING THE RISK OF CARDIOVASCULAR DISEASE,” issued on or about February 9, 2021. DRL denies that the ’751 patent was “duly and legally issued,” and any suggestion or implication that the ’751 patent is valid or enforceable. DRL also admits that a purported copy of the ’751 patent is attached as Exhibit D to the First Amended Complaint. DRL denies any and all remaining allegations of Paragraph 47.

48. Esperion is the assignee of, and holds all rights, title, and interest in the ’751 Patent.

**ANSWER:** Paragraph 48 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, “ESPERION THERAPEUTICS, INC.” is identified as the current assignee of the ’751 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 48, and therefore denies any and all remaining allegations of Paragraph 48.

49. The '751 Patent currently expires on March 14, 2036.

**ANSWER:** Paragraph 49 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book identifies the purported expiration date of the '751 patent as March 14, 2036. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 49, and therefore denies any and all remaining allegations of Paragraph 49.

50. U.S. Patent No. 11,744,816 (the "'816 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on September 5, 2023. A true and correct copy of the '816 Patent is attached hereto as "Exhibit E."

**ANSWER:** Paragraph 50 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '816 patent, titled "FIXED DOSE COMBINATIONS AND FORMULATIONS COMPRISING ETC1002 AND EZETIMIBE AND METHODS OF TREATING OR REDUCING THE RISK OF CARDIOVASCULAR DISEASE," issued on or about September 5, 2023. DRL denies that the '816 patent was "duly and legally issued," and any suggestion or implication that the '816 patent is valid or enforceable. DRL also admits that a purported copy of the '816 patent is attached as Exhibit E to the First Amended Complaint. DRL denies any and all remaining allegations of Paragraph 50.

51. Esperion is the assignee of, and holds all rights, title, and interest in the '816 Patent.

**ANSWER:** Paragraph 51 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "ESPERION THERAPEUTICS, INC." is identified as the current assignee of the '816 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the

remaining allegations of Paragraph 51, and therefore denies any and all remaining allegations of Paragraph 51.

52. The '816 Patent currently expires on March 14, 2036.

**ANSWER:** Paragraph 52 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book identifies the purported expiration date of the '816 patent as March 14, 2036. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 52, and therefore denies any and all remaining allegations of Paragraph 52.

53. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit F."

**ANSWER:** Paragraph 53 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '584 patent, titled "METHODS OF MAKING BEMPEDOIC ACID AND COMPOSITIONS OF THE SAME," issued on or about March 12, 2024. DRL denies that the '584 patent was "duly and legally issued," and any suggestion or implication that the '584 patent is valid or enforceable. DRL also admits that a purported copy of the '584 patent is attached as Exhibit F to the First Amended Complaint. DRL denies any and all remaining allegations of Paragraph 53.

54. Esperion is the assignee of, and holds all rights, title, and interest in the '584 Patent.

**ANSWER:** Paragraph 54 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "ESPERION THERAPEUTICS, INC." is identified as the current assignee of the '584 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the

remaining allegations of Paragraph 54, and therefore denies any and all remaining allegations of Paragraph 54.

55. The '584 Patent currently expires on June 19, 2040.

**ANSWER:** Paragraph 55 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book identifies the purported expiration date of the '584 patent as June 19, 2040. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 55, and therefore denies any and all remaining allegations of Paragraph 55.

56. All claims of the '799, '714, '511, '751, '816, and '584 Patents are valid, enforceable, and not expired.

**ANSWER:** Paragraph 56 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

#### **ESPERION'S NEXLETOL® PRODUCT**

57. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL® and NEXLIZET®.

**ANSWER:** Paragraph 57 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book identifies "ESPERION THERAPEUTICS INC" as the purported "Applicant Holder" for New Drug Application ("NDA") No. 211616 for NEXLETOL® and NDA No. 211617 for NEXLIZET®. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 57, and therefore denies any and all remaining allegations of Paragraph 57.

58. Esperion is the holder of New Drug Application (“NDA”) No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name “NEXLETOL®.” Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

**ANSWER:** Paragraph 58 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA’s Orange Book identifies “ESPERION THERAPEUTICS INC” as the purported “Applicant Holder” for NDA No. 211616 for NEXLETOL® and the “Approval Date” as February 21, 2020. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 58, and therefore denies any and all remaining allegations of Paragraph 58.

59. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

**ANSWER:** Paragraph 59 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the NEXLETOL® label (Revised 03/2024) states:

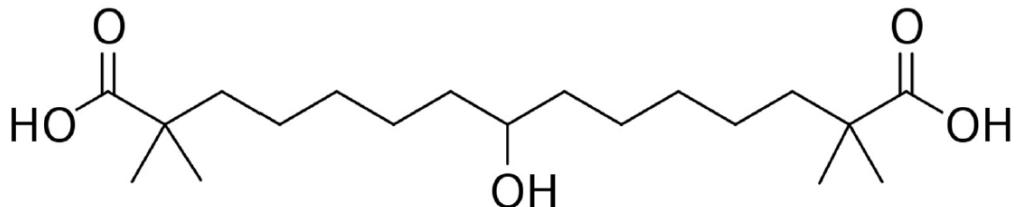
-----INDICATIONS AND USAGE-----

NEXLETOL, an adenosine triphosphate-citrate lyase (ACL) inhibitor, is indicated:

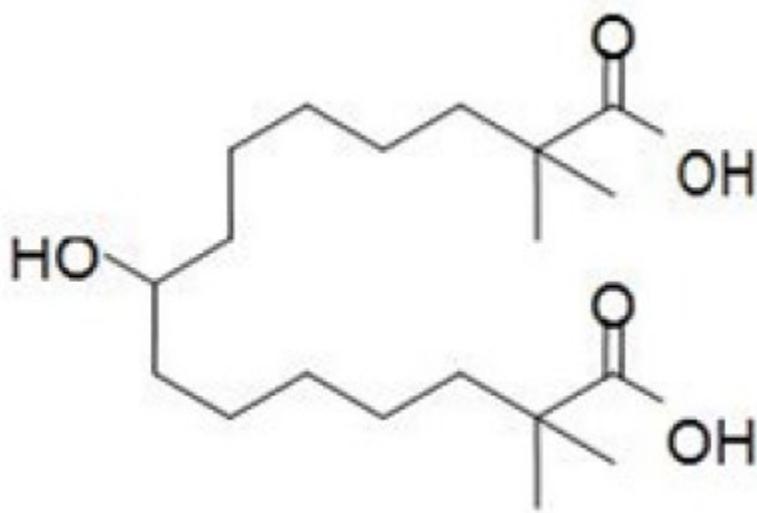
- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
  - established cardiovascular disease (CVD), or
  - a high risk for a CVD event but without established CVD. (1)
- As an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). (1)

DRL denies any and all remaining allegations of Paragraph 59.

60. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



**ANSWER:** Paragraph 60 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the NEXLETOL® label (Revised 03/2024) states “[t]he chemical name for bempedoic acid is 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid” and includes the following structural formula:



DRL denies any and all remaining allegations of Paragraph 60.

61. The claims of the '799, '714, '511, and '584 Patents cover NEXLETOL®.

**ANSWER:** Paragraph 61 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

62. The '799, '714, '511, and '584 Patents have been listed in connection with NEXLETOL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

**ANSWER:** Paragraph 62 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book includes the "Patent Data" shown below for NEXLETOL®:

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	7335799	12/03/2030	DS				03/06/2020
001	11613511	06/19/2040	DS				04/20/2023
001	11744816	03/14/2036			U-3883		04/19/2024
001	11760714	06/19/2040		DP			10/03/2023
001	11926584	06/19/2040			U-3873		04/09/2024

DRL denies any and all remaining allegations of Paragraph 62.

### **ESPERION'S NEXLIZET® PRODUCT**

63. Esperion is the holder of NDA No. 211617, which was approved by the FDA on February 26, 2020, for the marketing and sale of a combined bempedoic acid and ezetimibe product in the United States under the trade name “NEXLIZET®.” Esperion sells NEXLIZET® in the United States pursuant to NDA No. 211617.

**ANSWER:** Paragraph 63 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book identifies “ESPERION THERAPEUTICS INC” as the purported “Applicant Holder” for NDA No. 211617 for NEXLIZET® and the “Approval Date” as February 26, 2020. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 63, and therefore denies any and all remaining allegations of Paragraph 63.

64. NEXLIZET® is a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). The bempedoic acid component of NEXLIZET® is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

**ANSWER:** Paragraph 64 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the NEXLIZET® label (Revised 03/2024) states:

-----INDICATIONS AND USAGE-----

NEXLIZET, a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, is indicated:

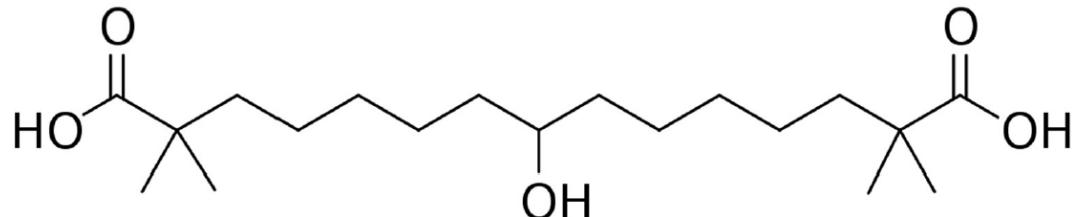
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). (1)

The bempedoic acid component of NEXLIZET is indicated:

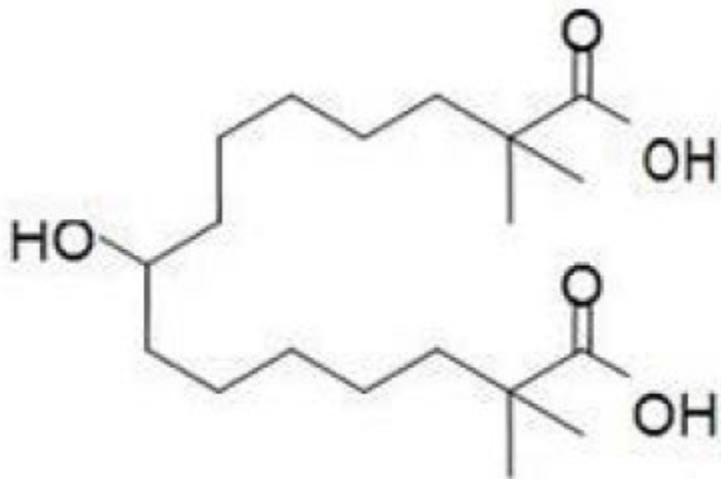
- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
  - established cardiovascular disease (CVD), or
  - a high risk for a CVD event but without established CVD. (1)

DRL denies any and all remaining allegations of Paragraph 64.

65. Bempedoic acid, one of the active pharmaceutical ingredients in NEXLIZET®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



**ANSWER:** Paragraph 65 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the NEXLIZET® label (Revised 03/2024) states “[t]he chemical name for bempedoic acid is 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid” and includes the following structural formula:



DRL denies any and all remaining allegations of Paragraph 65.

66. Ezetimibe, the other active pharmaceutical ingredient in NEXLIZET®, has the chemical name 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4- hydroxyphenyl)-2-azetidinone.

**ANSWER:** Paragraph 66 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the NEXLIZET® label (Revised 03/2024) states “[t]he chemical name for ezetimibe is 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone.” DRL denies any and all remaining allegations of Paragraph 66.

67. The claims of the '799, '714, '511, '751, '816, and '584 Patents cover NEXLIZET®.

**ANSWER:** Paragraph 67 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

68. The '799, '714, '511, '751, '816, and '584 Patents have been listed in connection with NEXLIZET® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”

**ANSWER:** Paragraph 68 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book includes the “Patent Data” shown below for NEXLIZET®:

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	7335799	12/03/2030	DS				03/06/2020
001	10912751	03/14/2036			U-3224 U-3884		10/14/2021
001	11613511	06/19/2040	DS				04/20/2023
001	11744816	03/14/2036			U-3692 U-3883		10/03/2023
001	11760714	06/19/2040		DP			10/03/2023
001	11926584	06/19/2040			U-3873		04/09/2024

DRL denies any and all remaining allegations of Paragraph 68.

#### **DRL'S BA ANDA PRODUCT**

69. By letter dated April 9, 2024, and received by Esperion via Federal Express no earlier than on April 10, 2024 (the “First NEXLETOL® Notice Letter”), DRL notified Esperion that DRL had submitted ANDA No. 219312 to the FDA for a generic version of NEXLETOL®.

**ANSWER:** Paragraph 69 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL’s Notice Letter dated April 9, 2024 (“First BA ANDA Notice Letter”) was sent to Esperion and notified Esperion that DRL’s BA ANDA had been submitted to FDA. DRL denies any and all remaining allegations of Paragraph 69.

70. The First NEXLETOL® Notice Letter states that DRL seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the DRL NEXLETOL® ANDA product before the expiration of the ’799, ’714, and ’511 Patents. Upon information and belief, DRL intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the DRL NEXLETOL® ANDA product promptly upon receiving FDA approval to do so.

**ANSWER:** Paragraph 70 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL’s First BA ANDA Notice Letter states that “DRL seeks to obtain approval to engage in the commercial manufacture, use or sale of DRL’s proposed product before the expiration” of the ’799 patent, the ’511 patent, and the ’714 patent. DRL denies any and all remaining allegations of Paragraph 70.

71. By submitting ANDA No. 219312, DRL has represented to the FDA that the DRL NEXLETOL® ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

**ANSWER:** Paragraph 71 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA ANDA Notice Letter states that “[t]he U.S. Food and Drug Administration ('FDA') has received an ANDA submitted by DRL containing any required bioavailability or bioequivalence data or information with respect to Bempedoic Acid Tablets, 180 mg.” DRL further admits that DRL's First BA ANDA Notice Letter states that “[t]he active ingredient present in DRL's proposed product is 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid commonly known as bempedoic acid; the strength is 180 mg; and the dosage form is a tablet.” DRL denies any and all remaining allegations of Paragraph 71.

72. In the First NEXLETOL® Notice Letter, DRL stated that ANDA No. 219312 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '799, '714, and '511 Patents. DRL also contended that the '799, '714, and '511 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the DRL NEXLETOL® ANDA Product.

**ANSWER:** Paragraph 72 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA ANDA Notice Letter states that “DRL has certified with the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ('Paragraph IV Certification') that the 799 patent, 511 patent, and 714 patent are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of DRL's proposed product for which DRL has submitted its ANDA.” DRL denies any and all remaining allegations of Paragraph 72.

73. Upon information and belief, DRL had knowledge of the '799, '714, and '511 Patents at least when it submitted ANDA No. 219312 to the FDA.

**ANSWER:** Paragraph 73 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that it was aware of the '799 patent, the '714

patent, and the '511 patent when it filed its Paragraph IV Certification to these patents in connection with DRL's BA ANDA. DRL denies any and all remaining allegations of Paragraph 73.

74. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product immediately and imminently upon approval of ANDA No. 219312 and prior to expiration of the '799, '714, and '511 Patents.

**ANSWER:** Paragraph 74 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

75. DRL's First NEXLETOL® Notice Letter identified invalidity and non-infringement positions with respect to the '799, '714 and '511 Patents and included limited information about the DRL NEXLETOL® ANDA Product. DRL's Offer of Confidential Access permitted access only to limited, unspecified portions of DRL's ANDAs on terms and conditions set by DRL.

**ANSWER:** Paragraph 75 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA ANDA Notice Letter included a confidential detailed statement of the factual and legal basis for DRL's Paragraph IV Certification that the '799 patent, the '511 patent, and the '714 patent are invalid, unenforceable, and/or will not be infringed. DRL further admits that DRL's First BA ANDA Notice Letter included an Offer of Confidential Access "to only those portions of DRL's ANDA that, in DRL's judgment, are needed by Esperion to determine whether an action under Section 355 should be filed within the statutory 45 days of the receipt of this letter." DRL denies any and all remaining allegations of Paragraph 75.

76. On April 15, 2024, Esperion first requested DRL send its proposed Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219312.

**ANSWER:** Paragraph 76 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that on April 15, 2024, Counsel for Esperion

requested “a MS Word version of your proposed Offer of Confidential Access so that we can consider it further with our client.” DRL denies any and all remaining allegations of Paragraph 76.

77. On April 16, 2024, DRL sent Esperion its proposed Offer of Confidential Access to permit Esperion access to limited portions of ANDA No. 219312 on terms and conditions set by DRL.

**ANSWER:** Paragraph 77 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that on April 16, 2024, DRL provided Counsel for Esperion with an MS Word version of DRL’s Offer of Confidential Access as requested. DRL denies any and all remaining allegations of Paragraph 77.

78. On April 29, 2024, Esperion sent DRL a proposed revision of the Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219312.

**ANSWER:** Paragraph 78 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that on April 29, 2024, Esperion sent DRL a proposed revision of the Offer of Confidential Access that sought broad, unnecessary disclosure of DRL’s highly proprietary information. DRL denies any and all remaining allegations of Paragraph 78.

79. DRL has not provided a substantive response to Esperion’s proposed revision of the Offer of Confidential Access. DRL refused to produce the entirety of ANDA No. 219312 to Esperion and refused to provide samples of its ANDA Product or components.

**ANSWER:** Paragraph 79 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL and Esperion did not reach an agreement regarding the terms of the Offer of Confidential Access. DRL denies any and all remaining allegations of Paragraph 79.

80. This action was commenced by the filing of a complaint on May 23, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First NEXLETOL® Notice Letter.

**ANSWER:** Paragraph 80 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA ANDA Notice Letter was dated April 9, 2024, and that Esperion filed a Complaint for patent infringement against Dr. Reddy's Inc. and Dr. Reddy's Ltd. on May 23, 2024. DRL denies any and all remaining allegations of Paragraph 80.

81. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 Patent.

**ANSWER:** Paragraph 81 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '584 patent issued on or about March 12, 2024. DRL denies any and all remaining allegations of Paragraph 81.

82. On or about April 9, 2024, and within thirty days of issuance of the '584 Patent, Esperion submitted Form 3542 identifying the '584 Patent for listing in the Orange Book for NEXLETOL®.

**ANSWER:** Paragraph 82 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book includes "Patent Data" for NEXLETOL® and identifies the '574 patent "Submission Date" as April 9, 2024. DRL denies any and all remaining allegations of Paragraph 82.

83. On information and belief, at some point on or after April 9, 2024, during the pendency of DRL's ANDA, DRL provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

**ANSWER:** Paragraph 83 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL provided a Paragraph IV Certification to the FDA that the '584 patent is invalid, unenforceable, or will not be infringed by the

manufacture, use, or sale of DRL's BA ANDA Product. DRL denies any and all remaining allegations of Paragraph 83.

84. By letter dated June 7, 2024, and received by Esperion via Federal Express no earlier than on June 10, 2024 (the "Second NEXLETOL® Notice Letter"), DRL sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. In the Second NEXLETOL® Notice Letter, DRL contended that the '584 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the DRL NEXLETOL® ANDA Product.

**ANSWER:** Paragraph 84 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's Notice Letter dated June 7, 2024 ("Second BA ANDA Notice Letter") was sent to Esperion and notified Esperion of DRL's Paragraph IV Certification to the '584 patent. DRL further admits that the Second BA ANDA Notice Letter states that "DRL has certified with the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ('Paragraph IV Certification') that the 584 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of DRL's proposed product for which DRL has submitted its ANDA." DRL denies any and all remaining allegations of Paragraph 84.

85. Upon information and belief, DRL had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 7, 2024.

**ANSWER:** Paragraph 85 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that it was aware of the '584 patent when it filed its Paragraph IV Certification to this patent in connection with DRL's BA ANDA. DRL denies any and all remaining allegations of Paragraph 85.

86. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product immediately and imminently upon approval of ANDA No. 219312 and prior to expiration of the '584 Patent.

**ANSWER:** Paragraph 86 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

87. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second NEXLETOL® Notice Letter and prior to DRL's answer to the original complaint filed May 23, 2024.

**ANSWER:** Paragraph 87 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's Second BA ANDA Notice Letter was dated June 7, 2024, that Esperion filed a Complaint for patent infringement against Dr. Reddy's Inc. and Dr. Reddy's Ltd. on May 23, 2024, and that Esperion filed its First Amended Complaint for patent infringement against Dr. Reddy's Inc. and Dr. Reddy's Ltd. on June 25, 2024. DRL denies any and all remaining allegations of Paragraph 87.

#### **DRL'S BA+E ANDA PRODUCT**

88. By letter dated April 29, 2024, and received by Esperion via Federal Express no earlier than on May 1, 2024 (the "First NEXLIZET® Notice Letter"), DRL notified Esperion that DRL had submitted ANDA No. 219331 to the FDA for a generic version of NEXLIZET® (the DRL NEXLIZET® ANDA Product").

**ANSWER:** Paragraph 88 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's Notice Letter dated April 29, 2024 ("First BA+E ANDA Notice Letter") was sent to Esperion and notified Esperion that DRL's BA+E ANDA had been submitted to FDA. DRL denies any and all remaining allegations of Paragraph 88.

89. The First NEXLIZET® Notice Letter states that DRL seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the DRL NEXLIZET® ANDA product before the expiration of the '799, '714, '511, '751, and '816 Patents. Upon information and belief, DRL intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the DRL NEXLIZET® ANDA product promptly upon receiving FDA approval to do so.

**ANSWER:** Paragraph 89 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA+E ANDA Notice Letter states that "DRL seeks to obtain approval to engage in the commercial manufacture, use or sale of DRL's proposed product before the expiration" of the '799 patent, the '751 patent, the '511 patent, the '816 patent, and the '714 patent. DRL denies any and all remaining allegations of Paragraph 89.

90. By submitting ANDA No. 219331, DRL has represented to the FDA that the DRL NEXLIZET® ANDA Product has the same active ingredient, dosage form, and strength as NEXLIZET® and is bioequivalent to NEXLIZET®.

**ANSWER:** Paragraph 90 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA+E ANDA Notice Letter states that "[t]he U.S. Food and Drug Administration ('FDA') has received an ANDA submitted by DRL containing any required bioavailability or bioequivalence data or information with respect to Bempedoic Acid and Ezetimibe Tablets, 180 mg/10 mg." DRL further admits that DRL's First BA+E ANDA Notice Letter states that "[t]he active ingredients present in DRL's proposed product are 8-hydroxy-2,2,14,14- tetramethylpentadecanedioic acid, commonly known as bempedoic acid and (3R,4S)-1-(4-Fluorophenyl)-3-[(S)-3-(4-fluorophenyl)-3-hydroxypropyl]-4-(4-hydroxyphenyl)-azetidin-2-one, commonly known as ezetimibe; the strength is 180 mg of bempedoic acid and 10 mg of ezetimibe; and the dosage form is a tablet." DRL denies any and all remaining allegations of Paragraph 90.

91. In the First NEXLIZET® Notice Letter, DRL stated that ANDA No. 219331 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '799, '714, '511, '751, and '816 Patents. DRL also contended that the '799, '714, '511, '751, and '816 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the DRL NEXLIZET® ANDA Product.

**ANSWER:** Paragraph 91 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA+E ANDA Notice Letter states that "DRL has certified with the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ('Paragraph IV Certification') that the 799 patent, 751 patent, 511 patent, 816 patent, and 714 patent are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of DRL's proposed product for which DRL has submitted its ANDA." DRL denies any and all remaining allegations of Paragraph 91.

92. Upon information and belief, DRL had knowledge of the '799, '714, '511, '751, and '816 Patents at least when it submitted ANDA No. 219331 to the FDA.

**ANSWER:** Paragraph 92 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that it was aware of the '799 patent, the '714 patent, the '511 patent, the '751 patent, and the '816 patent when it filed its Paragraph IV Certification to these patents in connection with DRL's BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 92.

93. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product immediately and imminently upon approval of ANDA No. 219331 and prior to the expiration of the '799, '714, '511, '751, and '816 Patents.

**ANSWER:** Paragraph 93 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

94. DRL's First NEXLIZET® Notice Letter identified invalidity and noninfringement positions with respect to the '799, '714, '511, '751, and '816 Patents and included limited information about the DRL NEXLIZET® ANDA Product. DRL's Offer of Confidential Access permitted access only to limited, unspecified portions of DRL's ANDAs on terms and conditions set by DRL.

**ANSWER:** Paragraph 94 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA+E ANDA Notice Letter included a confidential detailed statement of the factual and legal basis for DRL's Paragraph IV Certification that the '799 patent, the '751 patent, the '511 patent, the '816 patent, and the '714 patent are invalid, unenforceable, and/or will not be infringed. DRL further admits that DRL's First BA+E ANDA Notice Letter included an Offer of Confidential Access "to only those portions of DRL's ANDA that, in DRL's judgment, are needed by Esperion to determine whether an action under Section 355 should be filed within the statutory 45 days of the receipt of this letter." DRL denies any and all remaining allegations of Paragraph 94.

95. On April 15, 2024, Esperion requested DRL send its proposed Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219331.

**ANSWER:** Paragraph 95 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL denies that Esperion requested DRL's Offer of Confidential Access access to, among other things, the entirety of DRL's BA+E ANDA on April 15, 2024 (i.e., prior to the date of DRL's First BA+E ANDA Notice Letter).

96. DRL has not provided Esperion with any portions of its ANDA No. 219331 and refused to provide samples of its ANDA Product or components.

**ANSWER:** Paragraph 96 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL and Esperion did not reach an agreement regarding the terms of the Offer of Confidential Access. DRL denies any and all remaining allegations of Paragraph 96.

97. This action was commenced by the filing of a complaint on May 23, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First NEXLIZET® Notice Letter.

**ANSWER:** Paragraph 97 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's First BA+E ANDA Notice Letter was dated April 29, 2024, and that Esperion filed a Complaint for patent infringement against Dr. Reddy's Inc. and Dr. Reddy's Ltd. on May 23, 2024. DRL denies any and all remaining allegations of Paragraph 97.

98. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 Patent.

**ANSWER:** Paragraph 98 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '584 patent issued on or about March 12, 2024. DRL denies any and all remaining allegations of Paragraph 98.

99. On or about April 9, 2024, and within thirty days of issuance of the '584 Patent, Esperion submitted Form 3542 identifying the '584 Patent for listing in the Orange Book for NEXLIZET®.

**ANSWER:** Paragraph 99 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that the electronic version of FDA's Orange Book includes "Patent Data" for NEXLIZET® and identifies the '584 patent "Submission Date" as April 9, 2024. DRL denies any and all remaining allegations of Paragraph 99.

100. On information and belief, at some point on or after April 9, 2024, during the pendency of DRL's ANDA, DRL provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

**ANSWER:** Paragraph 100 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL provided a Paragraph IV Certification to the FDA that the '584 patent is invalid, unenforceable, or will not be infringed by the

manufacture, use, or sale of DRL's BA+E ANDA Product. DRL denies any and all remaining allegations of Paragraph 100.

101. By letter dated June 7, 2024, and received by Esperion via Federal Express no earlier than on June 10, 2024 (the "Second NEXLIZET® Notice Letter"), DRL sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. In the Second NEXLIZET® Notice Letter, DRL contended that the '584 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the DRL NEXLIZET® ANDA Product.

**ANSWER:** Paragraph 101 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's Notice Letter dated June 7, 2024 ("Second BA+E ANDA Notice Letter") was sent to Esperion and notified Esperion of DRL's Paragraph IV Certification to the '584 patent. DRL further admits that the Second BA+E ANDA Notice Letter states that "DRL has certified with the FDA pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ('Paragraph IV Certification') that the 584 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of DRL's proposed product for which DRL has submitted its ANDA." DRL denies any and all remaining allegations of Paragraph 101.

102. Upon information and belief, DRL had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 7, 2024.

**ANSWER:** Paragraph 102 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that it was aware of the '584 patent when it filed its Paragraph IV Certification to this patent in connection with DRL's BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 102.

103. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product immediately and imminently upon approval of ANDA No. 219331 and prior to expiration of the '584 Patent.

**ANSWER:** Paragraph 103 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, denied.

104. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second NEXLIZET® Notice Letter and prior to DRL's answer to the original complaint filed May 23, 2024.

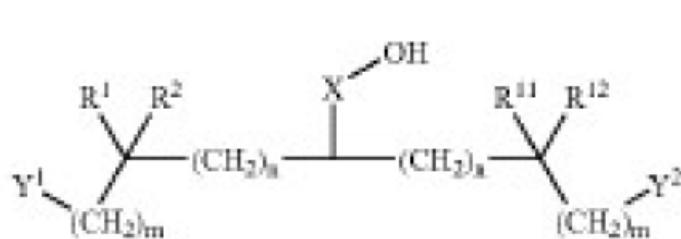
**ANSWER:** Paragraph 104 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that DRL's Second BA+E ANDA Notice Letter was dated June 7, 2024, that Esperion filed a Complaint for patent infringement against Dr. Reddy's Inc. and Dr. Reddy's Ltd. on May 23, 2024, and that Esperion filed its First Amended Complaint for patent infringement against Dr. Reddy's Inc. and Dr. Reddy's Ltd. on June 25, 2024. DRL denies any and all remaining allegations of Paragraph 104.

**COUNT I: U.S. PATENT NO. 7,335,799**  
**DRL'S BA ANDA PRODUCT**

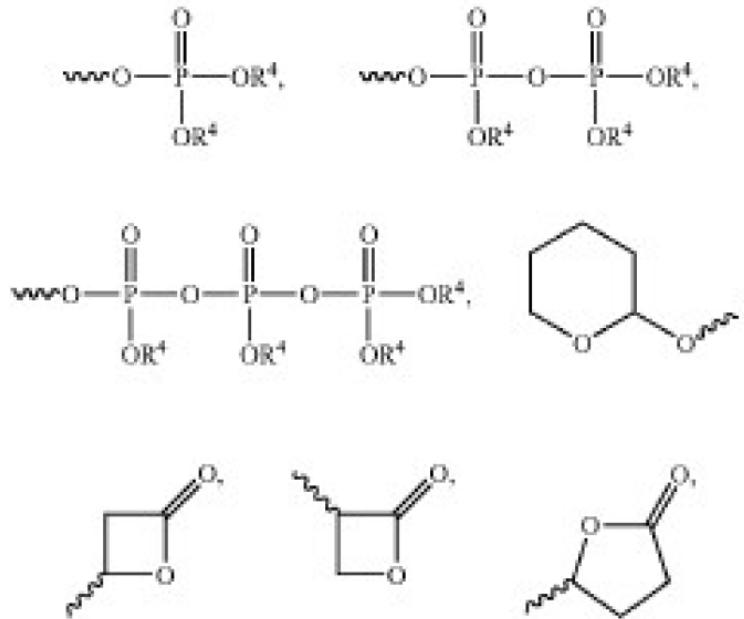
105. Esperion incorporates each of the preceding paragraphs 1-104 as if fully set forth herein.

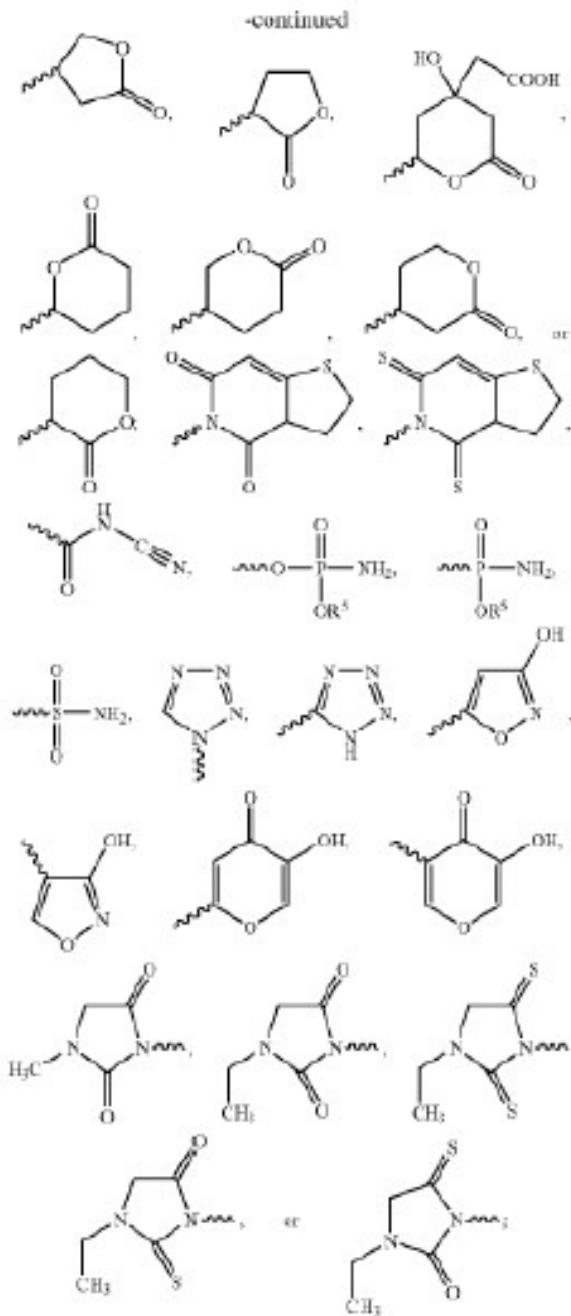
**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-104 as if fully set forth herein.

106. Claim 1 of the '799 Patent requires a compound of the formula (I):



or a pharmaceutically acceptable salt, hydrate, solvate or mixture thereof, wherein: (a) each occurrence of m is independently an integer ranging from 0 to 5; (b) each occurrence of n is independently an integer ranging from 3 to 7; (c) X is  $(\text{CH}_2)_2$  or Ph, wherein z is an integer from 0 to 4 and Ph is a 1,2-, 1,3-, or 1,4 substituted phenyl group; (d) each occurrence of  $\text{R}^1$ ,  $\text{R}^2$ ,  $\text{R}^{11}$ , and  $\text{R}^{12}$  is independently H,  $(\text{C}_1\text{-C}_6)$ alkyl,  $(\text{C}_2\text{-C}_6)$ alkenyl,  $(\text{C}_2\text{-C}_6)$ alkynyl, phenyl, or benzyl, wherein  $\text{R}^1$ ,  $\text{R}^2$ ,  $\text{R}^{11}$ , and  $\text{R}^{12}$  are not each simultaneously H; and (e) each occurrence of  $\text{Y}^1$  and  $\text{Y}^2$  is independently  $(\text{C}_1\text{-C}_6)$ alkyl, OH, COOH,  $\text{COOR}^3$ ,  $\text{SO}_3\text{H}$ ,

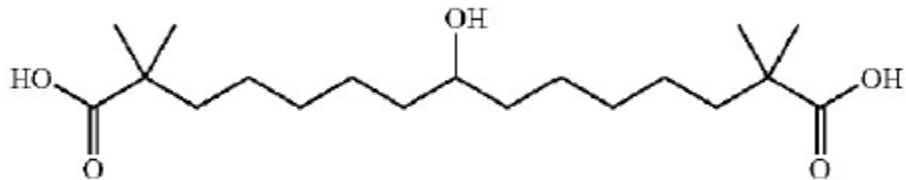




wherein: (i)  $Y^1$  and  $Y^2$  are not each simultaneously  $(C_1-C_6)$ alkyl; (ii)  $R^3$  is  $(C_1-C_6)$ alkyl,  $(C_2-C_6)$ alkenyl,  $(C_2-C_6)$ alkynyl, phenyl, or benzyl and is unsubstituted or substituted with one or more halo, OH,  $(C_1-C_6)$ alkoxy, or phenyl groups.

**ANSWER:** Paragraph 106 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 106 includes content copied from claim 1 of the '799 patent. DRL denies any and all remaining allegations of Paragraph 106.

107. Claim 12 of the '799 Patent requires a compound according to claim 1 wherein said compound has the structure:



8-Hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid;

or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

**ANSWER:** Paragraph 107 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 107 includes content copied from claim 12 of the '799 patent. DRL denies any and all remaining allegations of Paragraph 107.

108. DRL's submission of ANDA No. 219312 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product before the expiration of the '799 Patent constituted an act of infringement of the claims of the '799 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

109. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product prior to expiration of the '799 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claims 1 and 12 of the '799 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

110. Upon information and belief, upon FDA approval of ANDA No. 219312, DRL intends to, and will, infringe at least claims 1 and 12 of the '799 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, unless enjoined by the Court.

**ANSWER:** Denied.

111. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLETOL® Notice Letter, DRL has knowledge of the '799 Patent and knowledge that its DRL NEXLETOL® ANDA Product will infringe the '799 Patent.

**ANSWER:** Denied.

112. Upon information and belief, DRL intends to, and will, actively induce infringement of at least claims 1 and 12 of the '799 Patent under 35 U.S.C. § 271(b) when ANDA No. 219312 is approved by marketing the DRL NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '799 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

113. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claims 1 and 12 of the '799 Patent under 35 U.S.C. § 271(c) when ANDA No. 219312 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '799 Patent, and that the DRL NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

114. DRL's infringement is imminent because, among other things, DRL has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product before the expiration of the '799 Patent.

**ANSWER:** Denied.

115. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '799 Patent.

**ANSWER:** Denied.

116. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '799 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

117. Unless DRL is enjoined from directly or indirectly infringing the '799 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

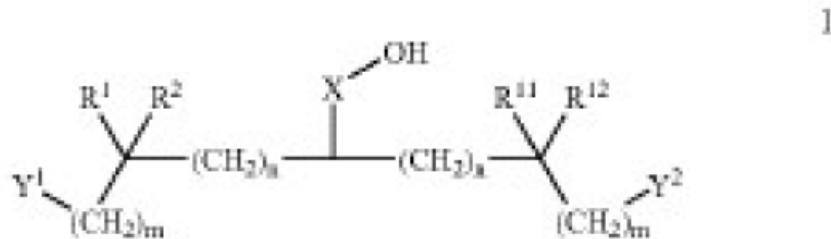
**ANSWER:** Denied.

**COUNT II: U.S. PATENT NO. 7,335,799**  
**DRL'S BA+E ANDA PRODUCT**

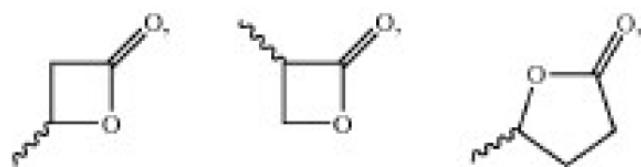
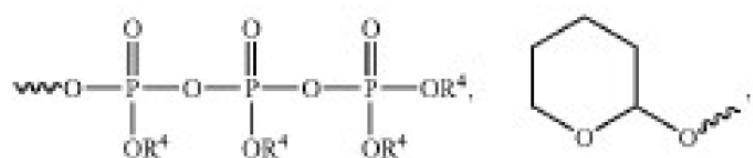
118. Esperion incorporates each of the preceding paragraphs 1-117 as if fully set forth herein.

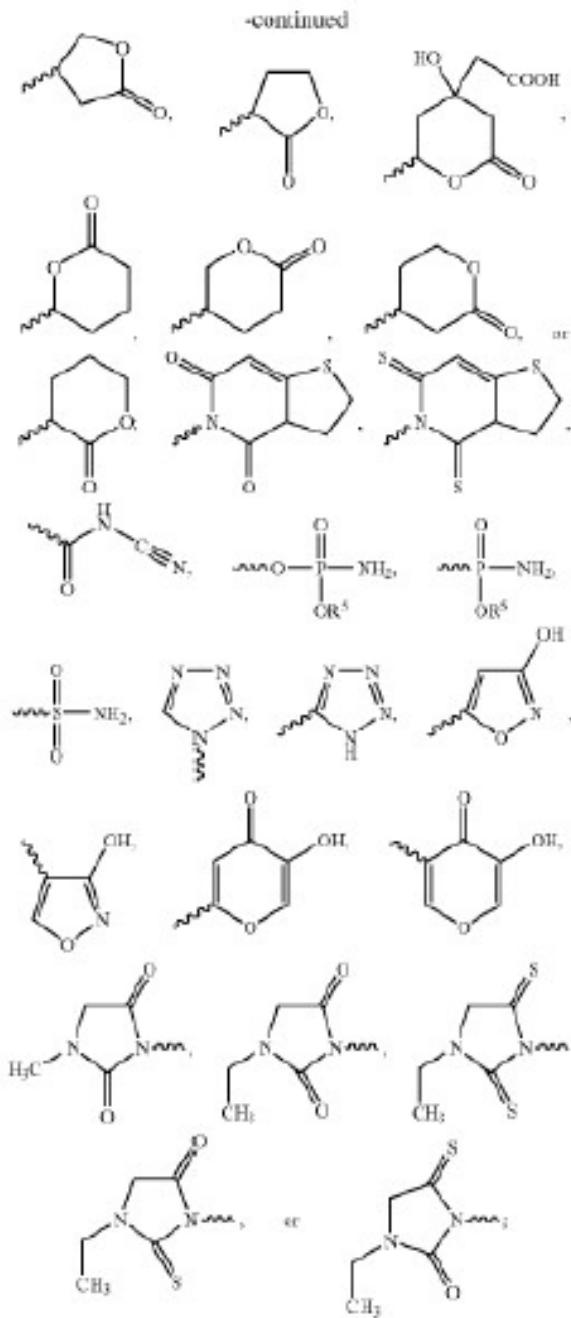
**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-117 as if fully set forth herein.

119. Claim 1 of the '799 Patent requires a compound of the formula (I):



or a pharmaceutically acceptable salt, hydrate, solvate or mixture thereof, wherein: (a) each occurrence of m is independently an integer ranging from 0 to 5; (b) each occurrence of n is independently an integer ranging from 3 to 7; (c) X is (CH<sub>2</sub>)<sub>2</sub> or Ph, wherein z is an integer from 0 to 4 and Ph is a 1,2-, 1,3-, or 1,4 substituted phenyl group; (d) each occurrence of R<sup>1</sup>, R<sup>2</sup>, R<sup>11</sup>, and R<sup>12</sup> is independently H, (C<sub>1</sub>-C<sub>6</sub>)alkyl, (C<sub>2</sub>-C<sub>6</sub>)alkenyl, (C<sub>2</sub>-C<sub>6</sub>)alkynyl, phenyl, or benzyl, wherein R<sup>1</sup>, R<sup>2</sup>, R<sup>11</sup>, and R<sup>12</sup> are not each simultaneously H; and (e) each occurrence of Y<sup>1</sup> and Y<sup>2</sup> is independently (C<sub>1</sub>-C<sub>6</sub>)alkyl, OH, COOH, COOR<sup>3</sup>, SO<sub>3</sub>H,

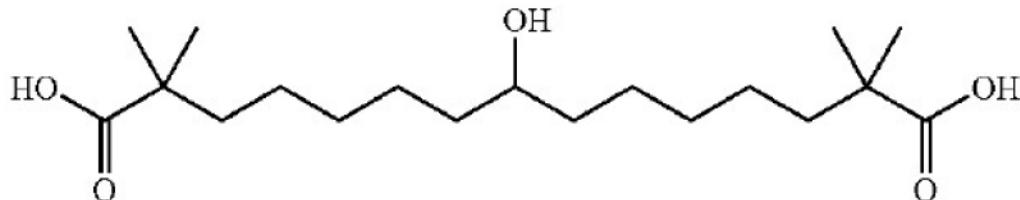




wherein: (i)  $Y^1$  and  $Y^2$  are not each simultaneously  $(C_1-C_6)$ alkyl; (ii)  $R^3$  is  $(C_1-C_6)$ alkyl,  $(C_2-C_6)$ alkenyl,  $(C_2-C_6)$ alkynyl, phenyl, or benzyl and is unsubstituted or substituted with one or more halo, OH,  $(C_1-C_6)$ alkoxy, or phenyl groups.

**ANSWER:** Paragraph 119 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 119 includes content copied from claim 1 of the '799 patent. DRL denies any and all remaining allegations of Paragraph 119.

120. Claim 12 of the '799 Patent requires a compound according to claim 1 wherein said compound has the structure:



8-Hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid;

or a pharmaceutically acceptable salt, hydrate, or solvate thereof.

**ANSWER:** Paragraph 120 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 120 includes content copied from claim 12 of the '799 patent. DRL denies any and all remaining allegations of Paragraph 120.

121. DRL's submission of ANDA No. 219331 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '799 Patent constituted an act of infringement of the claims of the '799 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

122. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product prior to expiration of the '799 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claims 1 and 12 of the '799 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

123. Upon information and belief, upon FDA approval of ANDA No. 219331, DRL intends to, and will, infringe at least claims 1 and 12 of the '799 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, unless enjoined by the Court.

**ANSWER:** Denied.

124. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLIZET® Notice Letter, DRL has knowledge of the '799 Patent and knowledge that its DRL NEXLIZET® ANDA Product will infringe the '799 Patent.

**ANSWER:** Denied.

125. Upon information and belief, DRL intends to, and will, actively induce infringement of at least claims 1 and 12 of the '799 Patent under 35 U.S.C. § 271(b) when ANDA No. 219331 is approved by marketing the DRL NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '799 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

126. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claims 1 and 12 of the '799 Patent under 35 U.S.C. § 271(c) when ANDA No. 219331 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '799 Patent, and that the DRL NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

127. DRL's infringement is imminent because, among other things, DRL has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '799 Patent.

**ANSWER:** Denied.

128. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '799 Patent.

**ANSWER:** Denied.

129. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '799 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

130. Unless DRL is enjoined from directly or indirectly infringing the '799 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

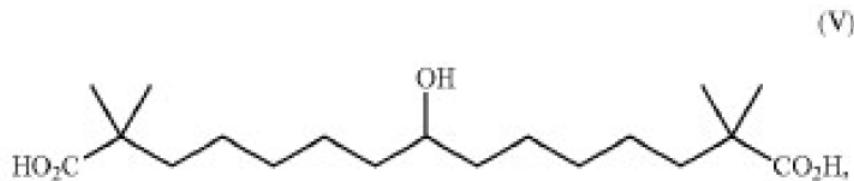
**ANSWER:** Denied.

**COUNT III: U.S. PATENT NO. 11,760,714**  
**DRL'S BA ANDA PRODUCT**

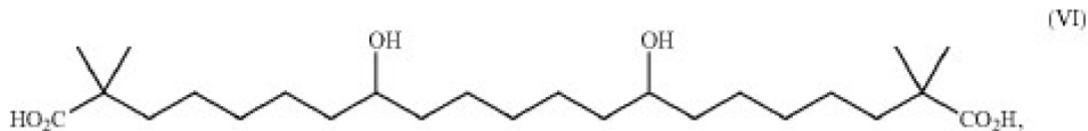
131. Esperion incorporates each of the preceding paragraphs 1-130 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-130 as if fully set forth herein.

132. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

**ANSWER:** Paragraph 132 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 132 includes content copied from claim 1 of the '714 patent. DRL denies any and all remaining allegations of Paragraph 132.

133. DRL's submission of ANDA No. 219312 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

134. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product prior to expiration of the '714 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

135. Upon information and belief, upon FDA approval of ANDA No. 219312, DRL intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, unless enjoined by the Court.

**ANSWER:** Denied.

136. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLETOL® Notice Letter, DRL has knowledge of the '714 Patent and knowledge that its DRL NEXLETOL® ANDA Product will infringe the '714 Patent.

**ANSWER:** Denied.

137. Upon information and belief, DRL intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219312 is approved by marketing the DRL NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

138. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219312 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the DRL NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

139. DRL's infringement is imminent because, among other things, DRL has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product before the expiration of the '714 Patent.

**ANSWER:** Denied.

140. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

**ANSWER:** Denied.

141. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

142. Unless DRL is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

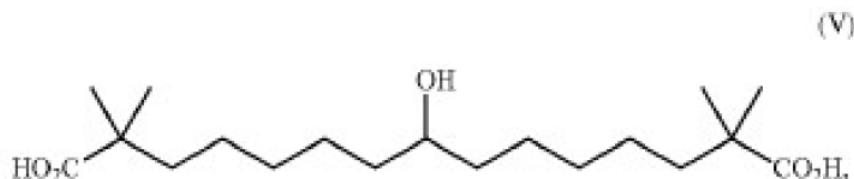
**ANSWER:** Denied.

**COUNT IV: U.S. PATENT NO. 11,760,714**  
**DRL'S BA+E ANDA PRODUCT**

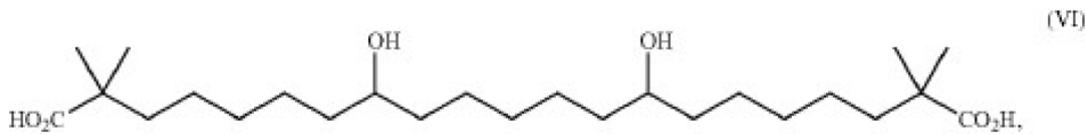
143. Esperion incorporates each of the preceding paragraphs 1-142 as if fully set forth

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-142 as if fully set forth herein.

144. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

**ANSWER:** Paragraph 144 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 144 includes content copied from claim 1 of the '714 patent. DRL denies any and all remaining allegations of Paragraph 144.

145. DRL's submission of ANDA No. 219331 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

146. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product prior to expiration of the '714 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

147. Upon information and belief, upon FDA approval of ANDA No. 219331, DRL intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, unless enjoined by the Court.

**ANSWER:** Denied.

148. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLIZET® Notice Letter, DRL has knowledge of the '714 Patent and knowledge that its DRL NEXLIZET® ANDA Product will infringe the '714 Patent.

**ANSWER:** Denied.

149. Upon information and belief, DRL intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219331 is approved by marketing the DRL NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

150. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219331 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the DRL NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

151. DRL's infringement is imminent because, among other things, DRL has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '714 Patent.

**ANSWER:** Denied.

152. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

**ANSWER:** Denied.

153. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

154. Unless DRL is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

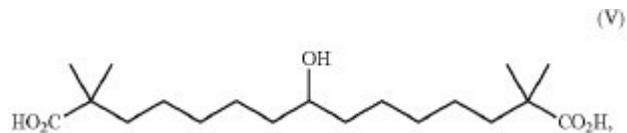
**ANSWER:** Denied.

**COUNT V: U.S. PATENT NO. 11,613,551**  
**DRL'S BA ANDA PRODUCT**

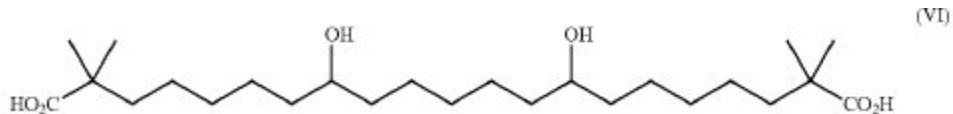
155. Esperion incorporates each of the preceding paragraphs 1-154 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-154 as if fully set forth herein.

156. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles ( $2\theta$ ):  $10.3\pm0.2$ ,  $10.4\pm0.2$ ,  $17.9\pm0.2$ ,  $18.8\pm0.2$ ,  $19.5\pm0.2$ , and  $20.7\pm0.2$ .

**ANSWER:** Paragraph 156 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 156 includes content copied from claim 1 of the '511 patent. DRL denies any and all remaining allegations of Paragraph 156.

157. DRL's submission of ANDA No. 219312 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

158. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product prior to expiration of the '511 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

159. Upon information and belief, upon FDA approval of ANDA No. 219312, DRL intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, unless enjoined by the Court.

**ANSWER:** Denied.

160. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLETOL® Notice Letter, DRL has knowledge of the '511 Patent and knowledge that its DRL NEXLETOL® ANDA Product will infringe the '511 Patent.

**ANSWER:** Denied.

161. Upon information and belief, DRL intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219312 is approved by marketing the DRL NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

162. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219312 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the DRL NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

163. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

**ANSWER:** Denied.

164. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

165. Unless DRL is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

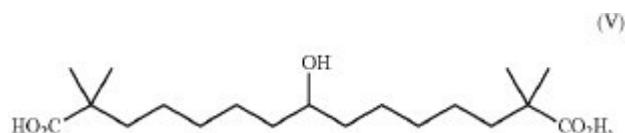
**ANSWER:** Denied.

**COUNT VI: U.S. PATENT NO. 11,613,551**  
**DRL'S BA+E ANDA PRODUCT**

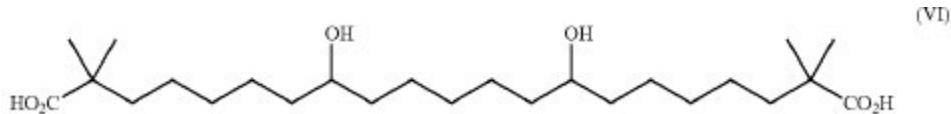
166. Esperion incorporates each of the preceding paragraphs 1-165 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-165 as if fully set forth herein.

167. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles ( $2\theta$ ):  $10.3\pm0.2$ ,  $10.4\pm0.2$ ,  $17.9\pm0.2$ ,  $18.8\pm0.2$ ,  $19.5\pm0.2$ , and  $20.7\pm0.2$ .

**ANSWER:** Paragraph 167 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 167 includes content copied from claim 1 of the '511 patent. DRL denies any and all remaining allegations of Paragraph 167.

168. DRL's submission of ANDA No. 219331 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

169. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product prior to expiration of the '511 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

170. Upon information and belief, upon FDA approval of ANDA No. 219331, DRL intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, unless enjoined by the Court.

**ANSWER:** Denied.

171. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLIZET® Notice Letter, DRL has knowledge of the '511 Patent and knowledge that its DRL NEXLIZET® ANDA Product will infringe the '511 Patent.

**ANSWER:** Denied.

172. Upon information and belief, DRL intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219331 is approved by marketing the DRL NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

173. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219331 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the DRL NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

174. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

**ANSWER:** Denied.

175. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

176. Unless DRL is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

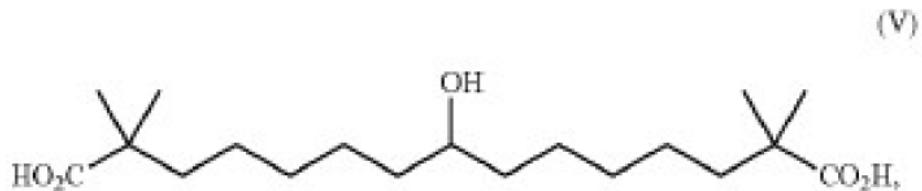
**ANSWER:** Denied.

**COUNT VII: U.S. PATENT NO. 11,926,584**  
**DRL'S BA ANDA PRODUCT**

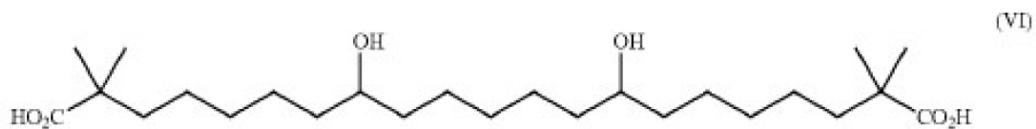
177. Esperion incorporates each of the preceding paragraphs 1-176 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-176 as if fully set forth herein.

178. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



**ANSWER:** Paragraph 178 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 178 includes content copied from claim 1 of the '584 patent. DRL denies any and all remaining allegations of Paragraph 178.

179. DRL's submission of ANDA No. 219312 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

180. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLETOL® ANDA Product prior to expiration of the '584 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

**ANSWER:** Denied.

181. Upon information and belief, upon FDA approval of DRL's ANDA No. 219312, DRL will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the DRL NEXLETOL® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

**ANSWER:** Denied.

182. Upon information and belief, DRL specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219312 is approved by marketing the DRL NEXLETOL® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

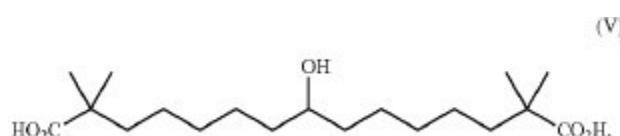
183. Upon information and belief, DRL's ANDA No. 219312 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the DRL NEXLETOL® ANDA Product.

**ANSWER:** Paragraph 183 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that a proposed package insert is included in DRL's BA ANDA. DRL denies any and all remaining allegations of Paragraph 183.

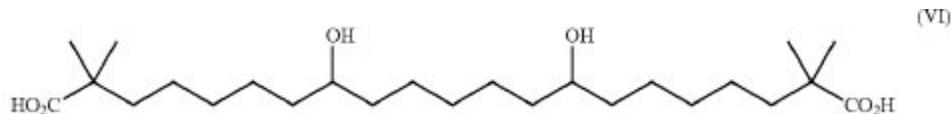
184. Upon information and belief, upon FDA approval of ANDA No. 219312, DRL intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, unless enjoined by the Court, and the DRL NEXLETOL® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

**ANSWER:** Denied.

185. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



**ANSWER:** Denied.

186. Upon information and belief, the use of the DRL NEXLETOL® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

187. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's Second NEXLETOL® Notice Letter, DRL has knowledge of the '584 Patent and knowledge that its DRL NEXLETOL® ANDA Product will infringe the '584 Patent.

**ANSWER:** Denied.

188. On information and belief, DRL is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the DRL NEXLETOL® ANDA Product at least according to DRL's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

**ANSWER:** Denied.

189. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219312 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the DRL NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

190. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

**ANSWER:** Denied.

191. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

192. Unless DRL is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

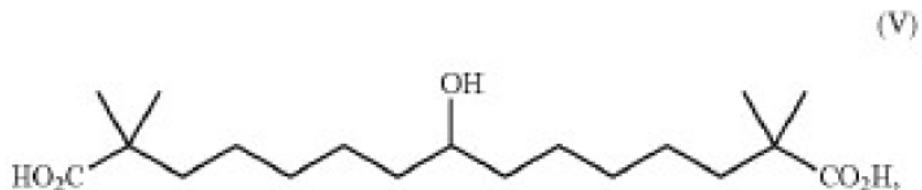
**ANSWER:** Denied.

**COUNT VIII: U.S. PATENT NO. 11,926,584**  
**DRL'S BA+E ANDA PRODUCT**

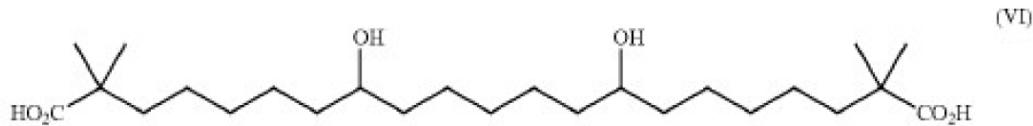
193. Esperion incorporates each of the preceding paragraphs 1-192 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-192 as if fully set forth herein.

194. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human atherapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



**ANSWER:** Paragraph 194 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Paragraph 194 includes content copied from claim 1 of the '584 patent. DRL denies any and all remaining allegations of Paragraph 194.

195. DRL's submission of ANDA No. 219331 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

196. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product prior to expiration of the '584 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

**ANSWER:** Denied.

197. Upon information and belief, upon FDA approval of DRL's ANDA No. 219331, DRL will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the DRL NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

**ANSWER:** Denied.

198. Upon information and belief, DRL specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219331 is approved by marketing the DRL NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

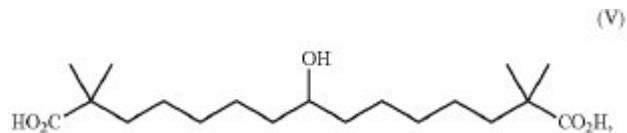
199. Upon information and belief, DRL's ANDA No. 219331 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the DRL NEXLIZET® ANDA Product.

**ANSWER:** Paragraph 199 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that a proposed package insert is included in DRL's BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 199.

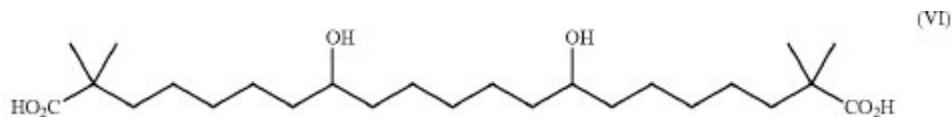
200. Upon information and belief, upon FDA approval of ANDA No. 219331, DRL intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, unless enjoined by the Court, and the DRL NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

**ANSWER:** Denied.

201. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



**ANSWER:** Denied.

202. Upon information and belief, the use of the DRL NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

203. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's Second NEXLIZET® Notice Letter, DRL has knowledge of the '584 Patent and knowledge that its DRL NEXLIZET® ANDA Product will infringe the '584 Patent.

**ANSWER:** Denied.

204. On information and belief, DRL is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the DRL NEXLIZET® ANDA Product at least according to DRL's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

**ANSWER:** Denied.

205. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219331 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the DRL NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

206. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

**ANSWER:** Denied.

207. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

208. Unless DRL is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

**ANSWER:** Denied.

**COUNT IX: U.S. PATENT NO. 10,912,751**  
**DRL'S BA+E ANDA PRODUCT**

209. Esperion incorporates each of the preceding paragraphs 1-208 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-208 as if fully set forth herein.

210. Claim 1 of the '751 Patent claims a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8- hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14- tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

**ANSWER:** Paragraph 210 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that claim 1 of the '751 patent recites the following:

**1. A method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.**

DRL denies any and all remaining allegations of Paragraph 210.

211. DRL's submission of ANDA No. 219331 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '751 Patent constituted an act of infringement of the claims of the '751 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

212. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product prior to expiration of the '751 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '751 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

**ANSWER:** Denied.

213. Upon information and belief, upon FDA approval of DRL's ANDA No. 219331, DRL will infringe at least claim 1 of the '751 Patent by making, using, offering to sell, and selling the DRL NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '751 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

**ANSWER:** Denied.

214. Upon information and belief, DRL specifically intends to, and will, actively induce infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(b) when ANDA No. 219331 is approved by marketing the DRL NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '751 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

215. Upon information and belief, DRL's ANDA No. 219331 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the DRL NEXLIZET® ANDA Product.

**ANSWER:** Paragraph 215 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that a proposed package insert is included in DRL's BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 215.

216. Upon information and belief, upon FDA approval of ANDA No. 219331, DRL intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, unless enjoined by the Court, and the DRL NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

**ANSWER:** Denied.

217. On information and belief, the proposed package insert will include a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

**ANSWER:** Denied.

218. Upon information and belief, the use of the DRL NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '751 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

219. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLIZET® Notice Letter, DRL has knowledge of the '751 Patent and knowledge that its DRL NEXLIZET® ANDA Product will infringe the '751 Patent.

**ANSWER:** Denied.

220. On information and belief, DRL is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the DRL NEXLIZET® ANDA Product at least according to DRL's proposed package insert and, therefore, will directly infringe at least claim 1 of the '751 Patent.

**ANSWER:** Denied.

221. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(c) when ANDA No. 219331 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '751 Patent, and that the DRL NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

222. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '751 Patent.

**ANSWER:** Denied.

223. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '751 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

224. Unless DRL is enjoined from directly or indirectly infringing the '751 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

**ANSWER:** Denied.

**COUNT X: U.S. PATENT NO. 11,744,816**  
**DRL'S BA+E ANDA PRODUCT**

225. Esperion incorporates each of the preceding paragraphs 1-224 as if fully set forth herein.

**ANSWER:** DRL restates and incorporates by reference each of its responses to Paragraphs 1-224 as if fully set forth herein.

226. Claim 1 of the '816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

**ANSWER:** Paragraph 226 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that claim 1 of the '816 patent recites the following:

**1. A method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.**

DRL denies any and all remaining allegations of Paragraph 226.

227. DRL's submission of ANDA No. 219331 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product before the expiration of the '816 Patent constituted an act of infringement of the claims of the '816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

228. DRL's commercial manufacture, use, offer for sale, sale, and/or importation of the DRL NEXLIZET® ANDA Product prior to expiration of the '816 Patent, and DRL's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

**ANSWER:** Denied.

229. Upon information and belief, upon FDA approval of DRL's ANDA No. 219331, DRL will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the DRL NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

**ANSWER:** Denied.

230. Upon information and belief, DRL specifically intends to, and will, actively induce infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219331 is approved by marketing the DRL NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '816 Patent, unless enjoined by the Court.

**ANSWER:** Denied.

231. Upon information and belief, DRL's ANDA No. 219331 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the DRL NEXLIZET® ANDA Product.

**ANSWER:** Paragraph 231 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that a proposed package insert is included in DRL's BA+E ANDA. DRL denies any and all remaining allegations of Paragraph 231.

232. Upon information and belief, upon FDA approval of ANDA No. 219331, DRL intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, unless enjoined by the Court, and the DRL NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

**ANSWER:** Denied.

233. On information and belief, the proposed package insert will include a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

**ANSWER:** Denied.

234. Upon information and belief, the use of the DRL NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

235. Upon information and belief, by virtue of its listing in the Orange Book and identification in DRL's First NEXLIZET® Notice Letter, DRL has knowledge of the '816 Patent and knowledge that its DRL NEXLIZET® ANDA Product will infringe the '816 Patent.

**ANSWER:** Denied.

236. On information and belief, DRL is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the DRL NEXLIZET® ANDA Product at least according to DRL's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

**ANSWER:** Denied.

237. Upon information and belief, DRL intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219331 is approved, unless enjoined by the Court, because DRL knows that the DRL NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the DRL NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

**ANSWER:** Denied.

238. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

**ANSWER:** Denied.

239. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that DRL's making, using, offering to sell, selling, and/or importing the DRL NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

240. Unless DRL is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

**ANSWER:** Denied.

**PRAYER FOR RELIEF**

DRL denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief, or to any relief whatsoever, and further request that judgment be entered in favor of DRL, dismissing Plaintiffs' First Amended Complaint with prejudice, awarding DRL attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

**SEPERATE DEFENSES**

Without prejudice to the denials set forth in their Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiff, DRL avers and asserts the following defenses to the First Amended Complaint.

**FIRST DEFENSE**  
**(INVALIDITY)**

The claims of the '799 patent, the '751 patent, the '511 patent, the '816 patent, the '714 patent, and the '584 patent are invalid for failing to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

**SECOND DEFENSE**  
**(NON-INFRINGEMENT–ANDA NO. 219312)**

The manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempeidoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the '799 patent, the '511 patent, the '714 patent, or the '584 patent, either literally or under the doctrine of equivalents.

**THIRD DEFENSE**  
**(NO INDUCEMENT–ANDA NO. 219312)**

DRL has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '799 patent, the '511 patent, the '714 patent, or the '584 patent by, *inter alia*, manufacturing, using, selling, offering for sale, importing, and/or marketing DRL's proposed bempeidoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312.

**FOURTH DEFENSE**  
**(NO CONTRIBUTORY INFRINGEMENT–ANDA NO. 219312)**

DRL has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '799 patent, the '511 patent, the '714 patent, or the '584 patent by, *inter alia*, manufacturing, using, selling, offering for sale, importing, and/or marketing DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312.

**FIFTH DEFENSE**  
**(NON-INFRINGEMENT–ANDA NO. 219331)**

The manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10 mg, that are the subject of DRL's ANDA No. 219331, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the '799 patent, the '751 patent, the '511 patent, the '816 patent, the '714 patent, or the '584 patent, either literally or under the doctrine of equivalents.

**SIXTH DEFENSE**  
**(NO INDUCEMENT–ANDA NO. 219331)**

DRL has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '799 patent, the '751 patent, the '511 patent, the '816 patent, the '714 patent, or the '584 patent by, *inter alia*, manufacturing, using, selling, offering for sale, importing, and/or marketing DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10 mg, that are the subject of DRL's ANDA No. 219331.

**SEVENTH DEFENSE**  
**(NO CONTRIBUTORY INFRINGEMENT–ANDA NO. 219331)**

DRL has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '799 patent, the '751 patent, the '511 patent, the '816 patent, the '714 patent, or the '584 patent by, *inter alia*, manufacturing, using, selling, offering for

sale, importing, and/or marketing DRL's proposed bempeboic acid and ezetimibe tablets, 180 mg/10 mg, that are the subject of DRL's ANDA No. 219331.

**EIGHTH DEFENSE**  
**(NO SUBJECT MATTER JURISDICTION)**

The Court lacks subject matter jurisdiction over this action solely for the claims against Dr. Reddy's Inc.

**NINTH DEFENSE**  
**(SAFE HARBOR)**

DRL is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

**TENTH DEFENSE**  
**(NO EXCEPTIONAL CASE)**

The First Amended Complaint fails to state a claim for exceptional case.

**ELEVENTH DEFENSE**  
**(FAILURE TO STATE A CLAIM)**

The First Amended Complaint fails to state a claim upon which relief can be granted.

**TWELFTH DEFENSE**  
**(ADDITIONAL DEFENSES)**

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

\* \* \*

## **COUNTERCLAIMS**

Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") (collectively, "DRL"), for their Counterclaims against Plaintiff/Counterclaim-Defendant Esperion Therapeutics, Inc. ("Plaintiff/Counterclaim-Defendant" or "Esperion") allege as follows:

### **THE PARTIES**

1. Dr. Reddy's Laboratories, Inc. is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.
2. Dr. Reddy's Laboratories, Ltd. is an entity organized and existing under the laws of India, having a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500034, India, which is in the state of Telangana.
3. On information and belief and according to the First Amended Complaint (D.I. 8 ¶ 2), Esperion Therapeutics, Inc. claims and purports to be a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

### **JURISDICTION AND VENUE**

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
6. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant because it has availed itself of the rights and privileges, and subjected itself to the

jurisdiction of this forum by suing DRL in this District, and, on information and belief, because Plaintiff/Counterclaim-Defendant conducts substantial business in, and has regular systemic contact with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

### **BACKGROUND**

8. On or about February 26, 2008, the U.S. Patent and Trademark Office (the “USPTO”) issued U.S. Patent No. 7,335,799 (the “’799 patent”).

9. On or about February 9, 2021, the USPTO issued U.S. Patent No. 10,912,751 (the “’751 patent”).

10. On or about March 28, 2023, the USPTO issued U.S. Patent No. 11,613,511 (the “’511 patent”).

11. On or about September 5, 2023, the USPTO issued U.S. Patent No. 11,744,816 (the “’816 patent”).

12. On or about September 19, 2023, the USPTO issued U.S. Patent No. 11,760,714 (the “’714 patent”).

13. On or about March 12, 2024, the USPTO issued U.S. Patent No. 11,926,584 (the “’584 patent”).

14. Plaintiff/Counterclaim-Defendant purports to be the assignee of, and holder of all rights, titles, and interests in the ’799 patent, the ’751 patent, the ’511 patent, the ’816 patent, the ’714 patent, and the ’584 patent (collectively, “Asserted Patents”) (D.I. 8 ¶¶ 38-54).

15. On or about June 25, 2024, Plaintiff/Counterclaim-Defendant sued DRL in this District alleging that DRL’s proposed bemedoic acid tablets, 180 mg, that are the

subject of DRL's ANDA No. 219312 infringe the '799 patent, the '511 patent, the '714 patent, and the '584 patent under 35 U.S.C. § 271(e)(2).

16. On or about June 25, 2024, Plaintiff/Counterclaim-Defendant sued DRL in this District alleging that DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10 mg, that are the subject of DRL's ANDA No. 219331 infringe the '799 patent, the '751 patent, the '511 patent, the '816 patent, the '714 patent, and the '584 patent under 35 U.S.C. § 271(e)(2).

17. There is an actual and justiciable controversy between the parties as to the alleged infringement and/or invalidity of the Asserted Patents.

**COUNT I**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '799 PATENT)**

18. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '799 patent.

20. One or more claims of the '799 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

21. DRL is entitled to a judicial declaration that the claims of the '799 patent are invalid.

**COUNT II**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '751 PATENT)**

22. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

23. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '751 patent.

24. One or more claims of the '751 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

25. DRL is entitled to a judicial declaration that the claims of the '751 patent are invalid.

**COUNT III**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '511 PATENT)**

26. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '511 patent.

28. One or more claims of the '511 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

29. DRL is entitled to a judicial declaration that the claims of the '511 patent are invalid.

**COUNT IV**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '816 PATENT)**

30. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

31. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '816 patent.

32. One or more claims of the '816 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

33. DRL is entitled to a judicial declaration that the claims of the '816 patent are invalid.

**COUNT V**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '714 PATENT)**

34. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

35. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '714 patent.

36. One or more claims of the '714 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

37. DRL is entitled to a judicial declaration that the claims of the '714 patent are invalid.

**COUNT VI**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '584 PATENT)**

38. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

39. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '584 patent.

40. One or more claims of the '584 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

41. DRL is entitled to a judicial declaration that the claims of the '584 patent are invalid.

**COUNT VII**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '799 PATENT-ANDA NO. 219312)**

42. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

43. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 would infringe any valid and/or enforceable claim of the '799 patent.

44. DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '799 patent.

45. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not

infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '799 patent.

**COUNT VIII**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '511 PATENT-ANDA NO. 219312)**

46. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

47. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 would infringe any valid and/or enforceable claim of the '511 patent.

48. DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '511 patent.

49. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '511 patent.

**COUNT IX**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '714 PATENT-ANDA NO. 219312)**

50. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

51. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempeidoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 would infringe any valid and/or enforceable claim of the '714 patent.

52. DRL's proposed bempeidoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '714 patent.

53. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempeidoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '714 patent.

**COUNT X**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '584 PATENT-ANDA NO. 219312)**

54. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

55. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempeidoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 would infringe any valid and/or enforceable claim of the '584 patent.

56. DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '584 patent.

57. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '584 patent.

**COUNT XI**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '799 PATENT-ANDA NO. 219331)**

58. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

59. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 would infringe any valid and/or enforceable claim of the '799 patent.

60. DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '799 patent.

61. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have

not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '799 patent.

**COUNT XII**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '751 PATENT-ANDA NO. 219331)**

62. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

63. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 would infringe any valid and/or enforceable claim of the '751 patent.

64. DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '751 patent.

65. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '751 patent.

**COUNT XIII**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '511 PATENT-ANDA NO. 219331)**

66. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

67. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 would infringe any valid and/or enforceable claim of the '511 patent.

68. DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '551 patent.

69. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '551 patent.

**COUNT XIV**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '816 PATENT-ANDA NO. 219331)**

70. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

71. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 would infringe any valid and/or enforceable claim of the '816 patent.

72. DRL's proposed bemedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '816 patent.

73. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bemedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '816 patent.

**COUNT XV**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '714 PATENT-ANDA NO. 219331)**

74. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

75. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bemedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 would infringe any valid and/or enforceable claim of the '714 patent.

76. DRL's proposed bemedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '714 patent.

77. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bemedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have

not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '714 patent.

**COUNT XVI**  
**(DECLARATORY JUDGMENT OF NON-INFRINGEMENT**  
**OF THE '584 PATENT-ANDA NO. 219331)**

78. DRL restates and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

79. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 would infringe any valid and/or enforceable claim of the '584 patent.

80. DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '584 patent.

81. DRL is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempedoic acid and ezetimibe tablets, 180 mg/10mg, that are the subject of DRL's ANDA No. 219331 have not infringed, do not infringe, and would not if marketed, infringe any valid and/or enforceable claim of the '584 patent.

**PRAYER FOR RELIEF**

WHEREFORE, DRL respectfully prays for judgment in its favor and against Counterclaim-Defendants:

(a) Declaring that the claims of the Asserted Patents are invalid;

- (b) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempeboic acid tablets, 180 mg, that are the subject of DRL's ANDA No. 219312, has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '799 patent, the '511 patent, the '714 patent, or the '584 patent.
- (c) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of DRL's proposed bempeboic acid and ezetimibe tablets, 180 mg/10 mg, that are the subject of DRL's ANDA No. 219331, has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '799 patent, the '751 patent, the '511 patent, the '816 patent, the '714 patent, or the '584 patent.
- (d) Ordering that Counterclaim-Defendants' First Amended Complaint be dismissed with prejudice and judgment entered in favor of DRL;
- (e) Declaring this case exceptional and awarding DRL its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and
- (e) Awarding DRL such other and further relief as the Court may deem just and proper.

CARELLA, BYRNE, CECCHI, OLSTEIN,  
BRODY & AGNELLO, P.C.

By: s/ Melissa E. Flax  
Melissa E. Flax  
mflax@carellabyrne.com

Dated: July 23, 2024

***OF COUNSEL (Pro Hac Vice Forthcoming)***

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Attorneys for Defendants,  
Dr. Reddy's Laboratories Inc., and  
Dr. Reddy's Laboratories Ltd.

**CERTIFICATION PURSUANT TO RULE 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding.

*s/ Melissa E. Flax*

Melissa E. Flax

Dated: July 23, 2024

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

*s/ Melissa E. Flax*

Melissa E. Flax

Dated: July 23, 2024

**CERTIFICATION OF SERVICE**

The undersigned attorney certifies that a copy of Defendants' foregoing Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended Complaint for Patent Infringement was filed via ECF and served on all counsel of record by electronic mail on July 23, 2024.

*s/ Melissa E. Flax*

Melissa E. Flax

Dated: July 23, 2024